

or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Office.

Furthermore, Applicants respectfully submit that entering this Amendment would allow Applicants to reply to the final rejections and place the application in condition for allowance or at least would place the application in better form for appeal, should the Office dispute the patentability of the pending claims.

III. Rejections under 35 U.S.C. § 103(a)

Yamahatsu

A. Claims 32 to 64, 67, and 74 are patentable.

The Office maintains its rejection of claims 32 to 64, 66 to 68, and 74 under 35 U.S.C. § 103(a) over Yamahatsu (EP 716,846) for the reasons found of record and for those found on pages 4 and 5 of the outstanding Office Action. Applicants respectfully submit that this rejection has been rendered moot. Claims 32 and 67 now recite "at least one peroxidase," *i.e.*, claim 32 now recites the original limitations of claim 65. The Office never rejected claim 65 over Yamahatsu. Applicants respectfully submit that Yamahatsu fails to teach or suggest "at least one peroxidase." Thus, there would have been no motivation to modify the teachings of Yamahatsu to reach the presently claimed invention of claims 32 to 64, 67, and 74. Additionally, the prior art fails to teach all the limitations of these claims. Applicants respectfully request that the rejection be withdrawn from each claim 32 to 64, 67, and 74.

B. Claims 75 and 76 are patentable.

Applicants cancelled claims 66 and 68. Claims 75 and 76 parallel claims 66 and 68, respectively, and are patentable. As noted above, claims 75 and 76 differ from claims 66 and 68 in two ways. First, claims 75 and 76 lack the compounds para-toluylenediamine and 2-chloro-para-phenylenediamine. Second, claims 75 and 76 lack the compound 2-aminophenol. Applicants believe that these three oxidation dyes were the only dyes in claims 66 and 68 that overlapped with the oxidation dyes of

Yamahatsu's list (p. 3, lines 3-15). Applicants respectfully submit that claims 75 and 76, lacking these three oxidation dyes, are patentable.

Yamahatsu in view of Husemeyer

A. *Claims 32 to 64, 67, and 74 are patentable.*

The Office maintains its rejection of claims 32 to 64, 66 to 68, 73, and 74 under 35 U.S.C. § 103(a) over Yamahatsu in view of Husemeyer (United States Patent No. 4,840,639) for the reasons of record and for the reasons on pages 5 and 6 of the outstanding Office Action. Yamahatsu fails to teach or suggest a composition comprising "at least one peroxidase" as presently recited in claims 32 to 64, 67, and 74. Applicants respectfully submit that Husemeyer also fails to teach or suggest "at least one peroxidase." Thus, regardless of the motivation to combine, there could have been no motivation to modify the teachings of Yamahatsu in view of Husemeyer to reach the presently claimed invention of claims 32 to 64, 67, and 74. Additionally, the prior art fails to teach all the limitations of these claims. Applicants respectfully request that the rejection be withdrawn from each claim from 32 to 64, 67, and 74.

B. *Claim 73, 75, and 76 are patentable.*

As admitted by the Office (Office Action of 5/9/00 at p. 5), Yamahatsu does not teach or suggest the 2- β -hydroxyethyl-para-phenylenediamine di-hydrochloride oxidation base recited in claims 73, 75, and 76. To remedy this deficiency, the Office combines the teachings of Yamahatsu with the teachings of Husemeyer, which discloses compositions comprising 1-hydroxyalkyl-2,5-diaminobenzenes (col. 1, lines 44-59) that embrace the 2- β -hydroxyethyl-para-phenylene diamine di-hydrochloride oxidation base of claims 73, 75, and 76.

The Office argues that it would have been obvious to substitute para-phenylenediamine and/or 2,5-diamine-toluene, from the Examples of Yamahatsu, with the 1-hydroxyalkyl-2,5-diaminobenzenes of Husemeyer. According to the Office, this combination and modification is desirable for two (2) reasons: (1) Yamahatsu is

concerned with uricase stability, which in turn suggests the storage stability of entire compositions; and (2) Husemeyer teaches that its compositions comprising 1-hydroxyalkyl-2,5-diaminobenzenes have improved properties, like shelf-life, toxicology, and improved color.

However, to prevent the use of hindsight based on the invention to defeat patentability of an invention, the Office must show a motivation to combine the references that create the case of obviousness. *M.P.E.P.* § 2143. In other words, the Office must show reasons that the skilled artisan, confronted with the same problems as the inventor and lacking knowledge of the claimed invention, would choose the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 USPQ2d 1453, 1457-8 (Fed. Cir. 1998). Importantly, with respect to this motivation, the Federal Circuit placed the burden on the Office to present "clear and particular" evidence showing motivation to combine. *In re Dembiczak*, 50 USPQ.2d 1614 (Fed. Cir. 1999).

Applicants especially disagree with the Office's first of its two (2) reasons, because there is no "particular" evidence that Yamahatsu and Husemeyer should be combined. In other words, the Office over-generalizes the teachings of Yamahatsu, which states: "The main object of the present invention is to improve stability of uricase in a hair dye composition" (p. 2, lines 18-21). Yamahatsu also teaches that one achieves uricase stability by using the effects of pH (Experiment 1), reducing agents (Experiment 2), pH adjusting agents (Experiment 3), water concentration (Experiment 4), and uricase activity (Experiment 5). Yamahatsu thus fails to suggest using the effect of oxidation bases on uricase stability or composition stability. Applicants respectfully submit that one skilled in the art would not have generalized Yamahatsu's teachings to find a suggestion to substitute ingredients unrelated to uricase stability.

Moreover, assuming, as the Office argues, Yamahatsu indirectly suggests the storage stability of entire compositions, nothing in either reference suggests the desire

to substitute ingredients, like Husemeyer's 1-hydroxyalkyl-2,5-diaminobenzenes, for improving stability of other ingredients, like para-phenylenediamine and/or 2,5-diamine-toluene. Even if Husemeyer's teachings are valid and true (Office Action at p. 6), they are not suggestive of the presently claimed invention. More specifically, Husemeyer states that its 1-hydroxyalkyl-2,5-diaminobenzenes have a "long shelf life" (col. 1, line 68-col. 2, line 1), which is a relative term, because Husemeyer never mentions the standard for comparison. Applicants respectfully submit that Husemeyer's statements about the toxicologic aspects (col. 3, lines 22-27) are also relative statements. Whatever these passages are relative to, they do not suggest the presently rejected claimed invention.

Husemeyer also allegedly teaches one oxidation base, one coupler, and an oxidant, most likely as hydrogen peroxide but definitely not an oxidant such as an enzyme/donor. Such oxidants Husemeyer fails to even acknowledge (col. 3, lines 46-50). The teachings of Husemeyer do not suggest the presently claimed invention because the teachings of Husemeyer must be compared to the claimed invention as a whole. The presently rejected claimed invention recites a composition comprising specific ingredients from "at least one first oxidation base," "at least one coupler," "at least one second oxidation base," "at least one enzyme," and "at least one donor." Husemeyer's prediction fails to consider *three ingredients* of the rejected claim 73. As such, Husemeyer's prediction is not relevant and thus not suggestive of the present claimed invention as a whole.

The prior art relied on does not provide a motivation to combine the teachings of Yamahatsu and Husemeyer to reach the claimed invention of claim 73. Thus, the rejection of claim 73 should be withdrawn.

Moreover, for analogous reasons, Applicants respectfully submit that claims 75 and 76 are patentable.

Cotteret in view of Tsujino

The Office still rejects claims 32 to 72 and 74 under 35 U.S.C. § 103(a) over Cotteret (United States Patent No. 5,514,188) in view of Tsujino (United States Patent No. 4,461,925) the reasons found of record and for those found on pages 7 and 8 of the outstanding Office Action. Applicants respectfully traverse this rejection, at least because there was no motivation for one of ordinary skill in the art to combine the teachings of these documents. Thus, a *prima facie* case of obviousness has not been established.

Cotteret recites a composition comprising "at least one oxidation dye precursor" chosen from p-aminophenols, "at least one oxidation dye precursor" chosen from p-phenylenediamines, a "coupling agent" 2-methyl-5-aminophenol, and "oxidizing agent" (col. 4, lines 27-44). Cotteret's "oxidizing agent" preferably includes hydrogen peroxide, but Cotteret also discloses urea peroxide, persalts, and alkali metal bromates (col. 5, lines 7-10). Cotteret mentions no other type of "oxidizing agent" (see col. 5, lines 7-10).

Thus, Cotteret is deficient, because, as admitted by the Office (p. 7 of Office Action), Cotteret does not teach or suggest a composition containing "at least one enzyme" and "at least one donor" as recited, e.g., in claims 32 and 67. Also, Cotteret fails to teach or suggest "at least one peroxidase" as recited, e.g., in claims 32 and 67.

To remedy these deficiencies, the Office combines the teachings of Cotteret with Tsujino, which teaches hair dye compositions containing, among other things, oxidation dyes, peroxidase, and enzyme/donor oxidizing systems. Tsujino does not exemplify a composition comprising an oxidation base and a coupler chosen from "at least one coupler" as presently recited, e.g., in independent claim 32.

The Office takes the position that it would have been obvious to one of ordinary skill in art to substitute the hydrogen peroxide oxidants of Cotteret with an enzyme/donor system as in Tsujino, because Tsujino teaches that enzyme/donor systems give superior results in effects ancillary to dyeing, e.g., decreased skin irritation

and damage to hair and skin. As argued in the prior response, however, the Office gives too much weight to Tsujino's generalized proclamations. When making the Office's proposed modification, one would have to trade superior dyeing capability and some skin irritation of Cotteret's oxidants for inferior dyeing capability and reduced skin irritation, *i.e.*, a trade-off.

Regarding the interpretation of the examples of Tsujino, the Office and Applicants disagree. More specifically, the Office believes the skilled artisan, armed with the teachings of Tsujino, would have predicted an equal dyeing capability between conventional oxidants (like those in Cotteret) and those of Tsujino (Office Action at p. 4). Tsujino, on the other hand, states: "According to the present invention [which uses enzyme/donor pairs], a good finish of hair can be obtained while retaining **almost** the same dyeing effect as that by using hydrogen peroxide as the oxidizing agent." (col. 5, lines 43-46) (emphasis added). This passage, in Applicants' view, means Tsujino's compositions would not have provided equal but lesser dyeing potential than complementary compositions using conventional oxidants. Applicants' view is further supported by Tsujino's Examples 1-1, 1-2, 1-4, where color was not as dark when compared with Examples 1-12 and 1-13, where complementary compositions used hydrogen peroxide. In Applicants' view, the skilled artisan would not have predicted an improvement in the dyeing properties of Cotteret's composition by substituting the hydrogen peroxide with the enzyme/donor pairs of Tsujino.

On the other hand, Tsujino does state that its enzyme/donor systems have lower levels of irritation when measured by the "interdigit dropping method" (col. 5, line 60). As a result, the skilled artisan would have had to trade superior dyeing capability and some skin irritation of Cotteret's oxidants for inferior dyeing capability and reduced skin irritation, *i.e.*, a trade-off. According to a recent Federal Circuit opinion, "[t]rade-offs often concern what is feasible, not what is, on balance, desirable." *Winner International Royalty Corp. v. Wang*, 53 U.S.P.Q.2d 1580, 1587 (Fed. Cir. 2000). A motivation to

combine requires desirability. While the documents cited by the Office may show that it is feasible to substitute Tsujino's enzyme/donor pairs for conventional oxidants, the documents of record fail to set forth that it would be desirable or reasonable for the skilled artisan to choose the inferior dyeing capability of Tsujino's enzyme/donor pairs for reduced skin irritation when compared with conventional oxidants.

As an aside, Tsujino's method seems favorable to its result. Specifically, in this method, Tsujino compared an 8.0% sodium bromate solution (Example 2-4) with a 2.0% uricase solution (Examples 2-1 and 2-2), wherein only 2.8 units/mg are the enzyme. Each solution was placed on the skin between each subject's fingers "twice a day for 6 days" (col. 7, lines 19-33). A panel judged the skin between the subject's fingers for roughness (col. 7, lines 34-51). The four (4) times more concentrated sodium bromate solution produced a harsher "degree of skin roughness" than the weaker uricase solution (Table 2). Applicants respectfully submit that Tsujino's comparison seems less than fair due to the discrepancy in concentrations of the bromate and enzyme solutions and the frequency of the applications.

Thus, although Tsujino notes that its oxidants are less irritating, nowhere do either Cotteret or Tsujino suggest a desirability for a new oxidant or a need for a less irritating oxidant. Specifically, from the evidence of record, it is unclear if consumers would prefer to trade the lower dyeing capability for a reduced skin irritation. Moreover, as just noted, Tsujino's skin irritation comparison seems unfair. So, because there would be no direct improvement expected with regard to the purpose of Cotteret, i.e., dyeing, and maybe an ancillary improvement of lower skin irritation, there would have been no desire to switch oxidants from hydrogen peroxide to the enzyme/donor pairs of Tsujino. This lack of desirability to combine or modify means the Office has failed to meet its burden to establish a *prima facie* case of obviousness.

In view of the above observations and arguments, Applicants respectfully submit that this invention was not obvious over the teachings of Cotteret in view of Tsujino at

the time this invention was made. Thus, Applicants respectfully request that the rejection be withdrawn with respect to each presently rejected claim.

Also, Applicants respectfully submit that claims 75 and 76 are patentable at least for the reasons already stated above.

VI. Obviousness-Type Double Patenting Rejection

The Office has rejected claims 32 to 74 under the judicially created doctrine of obviousness type double patenting as being unpatentable over the U.S. Application No. 09/319,165 for the reasons found of record and for those on page 4 of the outstanding Office Action. Applicants respectfully request to hold this provisional rejection in abeyance until an indication of allowable subject matter is made in this or the '165 application.

CONCLUSION

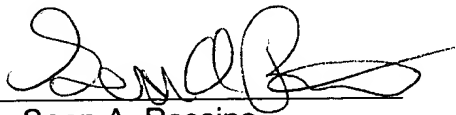
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of the pending claims and the timely allowance of the pending claims.

If the Office has any questions about this application, please contact Sean A. Passino at (202)408-6065.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 24, 2001

Enclosure: Appendix Complying with Rule 121

Appendix Complying with Rule 121

IN THE CLAIMS:

32. (Amended) A ready-to-use composition for the oxidation dyeing of keratin fibers, comprising:

- at least one first oxidation base chosen from para-phenylenediamine compounds other than para-phenylenediamine; double bases; ortho-aminophenols; heterocyclic bases; and acid-addition salts thereof,
- at least one second oxidation base chosen from para-aminophenols and acid-addition salts thereof,
- at least one coupler chosen from meta-aminophenols and acid-addition salts thereof,
- at least one enzyme chosen from 2-electron oxidoreductases, [and]
- at least one donor for said at least one enzyme, **and**
- **at least one peroxidase.**

67. (Twice Amended) A process for dyeing keratin fibers, comprising applying at least one ready-to-use dye composition for the oxidation dyeing of keratin fibers to said fibers and developing for a period of time sufficient to achieve desired coloration, wherein said ready-to-use dye composition comprises:

- at least one first oxidation base chosen from para-phenylenediamine compounds other than para-phenylenediamine; double bases; ortho-aminophenols; heterocyclic bases; and acid-addition salts thereof,
- at least one second oxidation base chosen from para-aminophenols and acid-addition salts thereof,
- at least one coupler chosen from meta-aminophenols and acid-addition salts thereof,
- at least one enzyme chosen from 2-electron oxidoreductases, [and]

- at least one donor for said at least one enzyme; and
- at least one peroxidase.